

REMARKS

Claims 1-10 are all the claims pending in the application; each of the claims has been rejected.

In order to further the prosecution of this application, claims 1-10 have been canceled and new claims 11-15, directed to a preferred embodiment, have been added. Applicants reserve the right to file one or more related applications directed to the subject matter cancelled from this application.

New claim 11 finds support in the specification at page 3, lines 23-26. Recitation of protective immunity within 21 days finds support in Example 2 and Table 1 (pages 8-10) where a protective response was clearly shown to have developed with 21 days of vaccination. As shown in Table 1, challenge doses of heterologous and homologous *Eimeria* strains gave rise to protective immunity.

New claim 12 finds support in the specification at page 8, line 5. New claim 13 finds support at page 5, lines 21-24. New claim 14 finds support at page 5, lines 5-6. New claim 15 finds support at page 3, lines 9-12.

No new matter has been introduced. Entry of the Amendment is earnestly solicited.

I. Claim Rejections – 35 U.S.C. §112, first paragraph

At paragraph 4 of the Office Action, the rejection of claims 1-10 under 35 U.S.C. §112, first paragraph, as being non-enabled, has been maintained.

In response, Applicants have cancelled claims 1-10, thus rendering this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Applicants note that included in the instant Amendment are new claims 11-15, reciting a preferred embodiment of the invention. As will be apparent from the recitation of claim 11, four different combinations of the *Eimeria* strains are included in the scope of the claim. The first comprises *Eimeria maxima* ARI-73/97 (deposit no. NM 98/02796), *Eimeria acervulina* ARI-77/97 (deposit no. NM 98/02794), and *Eimeria tenella* ARI-11/98 (deposit no. NM 98/02795). The second comprises *Eimeria maxima* ARI-73/97 (deposit no. NM 98/02796), *Eimeria acervulina* ARI-77/97 (deposit no. NM 98/02794), *Eimeria tenella* ARI-11/98 (deposit no. NM 98/02795), and *Eimeria necatrix* MCK01 (deposit no. NM 98/02797). The third comprises *Eimeria maxima* ARI-73/97 (deposit no. NM 98/02796), *Eimeria acervulina* ARI-77/97 (deposit no. NM 98/02794), *Eimeria tenella* ARI-11/98 (deposit no. NM 98/02795), and *Eimeria necatrix* ARI-MEDNEC₃+8 (deposit no. NM 99/02118). The fourth comprises all five of the strains recited in the claims. Support for new claim 11 is as indicated above in the remarks section.

Applicants assert that new claim 11, and dependent claims 12-15, are fully enabled. Applicants note that each of the five strains recited in the claims has been deposited under the terms of the Budapest Treaty with an approved depository agency (see Statement of Availability filed December 19, 2002). Thus, each of the strains recited in the claim is fully enabled.

Applicants further assert that given the teachings of the specification, and the experimental evidence therein, as well as that included with the Amendment filed in this application on December 19, 2002, the skilled artisan would have been enabled to practice the full scope of the invention as recited in new claims 11-15 at the time the application was filed.

II. Claim Rejections - 35 U.S.C. §§102 and 103

A. At paragraph 5 of the Office Action, the rejection of claims 1-4 and 7-10 under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, MacDonald et al. has been maintained.

The Examiner states that MacDonald et al. teaches a vaccine against coccidiosis in domestic fowls that contains attenuated precocious strains of *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, Applicants have cancelled claims 1-10, thus rendering this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

As noted above, new claims 11-15 have been added, reciting a preferred embodiment of the invention. Applicants assert that the disclosure of MacDonald et al. does not teach or suggest the subject matter of new claims 11-15.

The precocious *Eimeria* strains of MacDonald et al. are distinct organisms from those claimed in new claims 11-15. The organisms of MacDonald et al. are described as providing immunity only after 31 days heterologous or homologous *Eimeria* strain challenge. This is to be contrasted with the 21 day protective immune response realized through the use of the vaccine according to the present invention (see new claim 11).

Further, the organisms of MacDonald et al. have a prepatent time in the range 60-125 hours, as described at column 4, lines 34-40, of the patent. In contrast, the *Eimeria* vaccine strains of the present application have a sporulation time (equivalent to prepatent time) of between 18-30 hours, as described at page 8, line 5, of the specification, and as set forth in new claim 12.

The specification at page 3, lines 5-7, clearly sets out that the geographical isolation of Australia from foreign coccidial diseases ensures that the vaccine and vaccine strains described and claimed in the instant application are unique, and thus are neither disclosed nor suggested by the prior art.

Thus, Applicants assert that the disclosure of MacDonald et al. clearly shows that the organisms/vaccines described in MacDonald et al. are distinct from those claimed in the instant application. Moreover, neither are the specific vaccines of the invention in any way obvious.

B. At paragraph 6 of the Office Action, the rejection of claims 1-10 under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, Shirley has been maintained.

The Examiner states that Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, Applicants have cancelled claims 1-10, thus rendering this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

As noted above, new claims 11-15 have been added, reciting a preferred embodiment of the invention. Applicants assert that the disclosure of Shirley does not teach or suggest the subject matter of new claims 11-15.

The organisms of Shirley correspond to and are derived from the Houghton (H) strains of *Eimeria necatrix* isolated at Houghton in the United Kingdom (*see*, column 6, lines 25-30, of Shirley). Again, the strains of the present invention were discovered in Australian. The geographical isolation of Australia from the United Kingdom, and the variability of *Eimeria*

strains between continents, demonstrates to the skilled artisan that the organisms of Shirley are clearly distinct from those claimed in the present application.

Furthermore, the organisms of Shirley provide an immune response after 41 days, as described at column 10, lines 4 through 21, contrasted to a 21 day protective period according to the vaccine strains of the instant invention (see claim 11).

In addition, the vaccine strains of Shirley are also stated to have a 30% mortality rate, as described at column 3, lines 58-63. In contrast, the *Eimeria* vaccination organisms of the presently claimed invention are non-pathogenic, as shown for example in Table 1 where no treated bird suffered mortality.

Thus, the disclosure of Shirley does not teach or suggest the vaccines recited in new claims 11-15.

C. At paragraph 7 of the Office Action, the rejection of claims 1-10 under 35 U.S.C. §102(b) as being anticipated, or under 35 U.S.C. §103(a) as being obvious over, Schmatz et al. has been maintained.

The Examiner states that Schmatz et al. teaches live sporulated oocysts that are administered to one day old chickens to provide immunity against coccidiosis, and that this publication teaches vaccines which comprises *Eimeria* species, wherein the species are the same as those recited in the instant application.

In response, Applicants have cancelled claims 1-10, thus rendering this rejection moot. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

As noted above, new claims 11-15 have been added, reciting a preferred embodiment of the invention. Applicants assert that the disclosure of Schmatz et al. does not teach or suggest the subject matter of new claims 11-15.

Applicants note that the *Eimeria* organisms of Schmatz et al. are described at page 3, last line, to page 4, line 2, to be the organisms of the Shirley and MacDonald et al. references cited by the Examiner. For the reasons set forth above, neither Shirley or MacDonald et al. teach or suggest the vaccines of new claims 11-15.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Drew Hissong
Registration No. 44,765

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: October 8, 2003